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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/824,027

04/14/2004

Jennifer E. Van Eyk

PTQ-0058

6007

7590

05/18/2005

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EXAMINER

DESAI, ANAND U

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,027	EYK ET AL.	
	Examiner	Art Unit	
	Anand U. Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, drawn to claims 1, and 2 in the reply filed on February 11, 2005 is acknowledged. The traversal is on the ground(s) that including Groups I, III, and IV in the prosecution of this application should not place any undue or serious burden on the Examiner. This is not found persuasive because the search of the different inventions is not coextensive as exemplified by their different classifications, and would impose an undue or serious burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 3-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 11, 2005. This application contains claims 3-12 drawn to an invention nonelected with traverse in Paper filed February 11, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. New claims 13-20 have been added. Claims 1, 2, and 13-20 are currently pending and are under examination.

Priority

4. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(e). The priority date is April 14, 2003.

Information Disclosure Statement

5. The information disclosure statements (IDSs) submitted on December 29, 2004 and February 11, 2005 are being considered by the examiner. The Hanley et al. Journal of Physiology 544(3): 687-693 (2002) reference appears on both submitted IDSs, and is therefore being signed on the December 29, 2005 IDS form and crossed out of the February 11, 2005 IDS form.

Specification

6. The disclosure is objected to because of the following informalities:

7. On page 4, line 38, the word, "cased" appears to be intended to be "caused?" Suggest changing the word to "caused."

Appropriate correction is required.

Claim Objections

8. Claim 2 is objected to because of the following informalities:

9. The abbreviations, OxPhos, and TCA should be spelled out at the first occurrence.

Appropriate correction is required.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1, 2, 13-16, 19, and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 4 of copending Application No. 10/189,820. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application discloses a method for identifying a composition or event for preconditioning an organ and preventing cell injury or cell death comprising determining the ability of the composition or event to modulate a post-translational modification of an ATP synthase subunit or a precursor thereof in cells or to regulate ATP synthesis or hydrolysis in cells, wherein the ATP synthase subunit is ATP synthase β chain and the ATP synthase precursor is ATP synthase β chain precursor (see claims 3, and 4, current application, claims 1, 2, 13-16, 19, and 20).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1, 2, and 13-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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14. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the method of assessing the ability of the agent or event to modulate a preconditioning protein in a cell, tissue or organ. How does the method identify an agent or event?

15. Claim 14 recites the limitation "the protein complex" in 4th line of the claim. There is insufficient antecedent basis for this limitation in the claim. Suggest, "...a change in function of a protein complex or pathway of which the preconditioning protein is a member."

16. Claims 2, 13, and 15-20 are rejected for depending on rejected base claim 1.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

18. Claims 1, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Mochly-Rosen (U.S. Patent 6,165,977).

Mochly-Rosen discloses a method of reducing ischemic injury to a cell exposed to hypoxic conditions. The method includes introducing into the cell, prior to exposure to hypoxic

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conditions, a pharmaceutically effective amount of an isozyme-specific ϵ PKC (Protein Kinase C) agonist. The ϵ PKC agonist stimulates ϵ PKC, resulting in preconditioning of the cell. Mochly-Rosen discloses a method of identifying a compound effective to induce preconditioning in a cell, comprising contacting an ϵ PKC polypeptide containing a RACK (Receptors for Activated C-Kinase) binding site with an ϵ PKC agonist peptide in the presence and absence of a test compound for inducing preconditioning in a cell, measuring the binding between said ϵ PKC polypeptide and said ϵ PKC agonist peptide in the presence and absence of said test compound, and identifying said test compound as being effective to induce preconditioning if binding in the presence of the test compound is significantly decreased relative to binding in the absence of the test compound (see col. 4, lines 24-61, col. 14, line 45- col. 15, line 53, and claims 16-27). The activation of ϵ PKC signal transduction pathway produces a signaling mechanism to effect the preconditioning of a cell (current application, claims 1, 13, and 14).

19. Claims 1, 2, 13, 14, 15, 16, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Eyk et al. US 2003/0022220 A1.

Van Eyk et al. disclose a method for identifying a composition or event for preconditioning an organ and preventing cell injury or cell death comprising determining the ability of the composition or event to modulate a post-translational modification of an ATP synthase subunit or a precursor thereof in cells or to regulate ATP synthesis or hydrolysis in cells, wherein the ATP synthase subunit is ATP synthase β chain and the ATP synthase precursor is ATP synthase β chain precursor (see claims 3, and 4, claims 1, 2, 13, 14, 15, 16, 19, and 20).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claims 1, 13, 14, 15, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang, Y. et al. (J. Mol. Cell. Cardiol. 33: 2037-2046 (2001)).

Wang, Y. et al. disclose the opening of the mitochondrial K_{ATP} channel by nitric oxide as an end effector of cardioprotection during the "second window" of preconditioning. Wang, Y. et al. show nitric oxide results from diazoxide induced preconditioning, which leads to activation of NF κ B via the PKC- δ signaling pathway (see entire document, particularly Abstract, and Figure 5). One would have been motivated to identify an agent that activates the PKC- δ signaling pathway to open the mitochondrial K_{ATP} channel, because the open channels have been shown by Wang, Y. et al. to precondition cardiac tissue. Therefore it would have been obvious to the person having ordinary skill in the art to identify an agent that mimics the preconditioning effects

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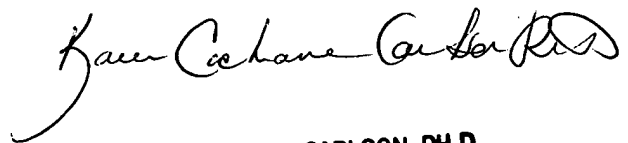
of diazoxide by designing an assay that screens for activators of the PKC- δ signaling pathway (current application, claims 1, 13, 14, 15, and 20).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 10, 2005



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER